FEB 1 0 2004

510(k) Summary——LabOne Micro-Plate Cotinine EIA

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is K033601.

Date of Summary:
August 25th, 2003

Correspondent:

Name:	Liuming Yu
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	Lenexa, Kansas 66210-9752
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Product Name:
Common Name: Micro-Plate Cotinine EIA
Trade Name: LabOne Micro-Plate Cotinine EIA
Classification Number: 862.3220

Substantially Equivalent Device:
Product: OraSure Micro-Plate Cotinine EIA
Manufactured by: OraSure® Technologies, Inc.
510(k) Number: K974234

Intended Use and Product Description:
LabOne Micro-Plate Cotinine EIA is a solid phase competitive enzyme immunoassay for the qualitative and semi-quantitative analysis of cotinine in oral fluid specimens collected with the OraSure® Oral Specimen Collection Device.

Comparison:
LabOne Micro-Plate Cotinine EIA is substantially equivalent to the OraSure Micro-Plate Cotinine EIA when used to qualitatively and semi-quantitatively test cotinine in oral fluid collected with the OraSure® Oral Fluid Specimen Collection Device

Comparison Performance Data:
Performance characteristic studies on precision, analytical sensitivity, interference and antibody cross-reactivity showed that the LabOne Micro-Plate Cotinine EIA is substantially equivalent to the OraSure Micro-Plate Cotinine EIA.
Results tested from self-claimed patient specimens and diluted samples with both the LabOne Micro-Plate Cotinine EIA and the OraSure Micro-Plate Cotinine EIA also showed that the

sample results from this two test systems are substantially equivalent when using self-claimed specimen results and urine results as references.

Conclusion:

LabOne Micro-Plate Cotinine EIA can be used to qualitatively and semi-quantitatively test cotinine in oral fluid collected with the OraSure® Oral Fluid Specimen Collection Device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 1 0 2004

LabOne, Inc
c/o Ms. Laura Danielson
Responsible Third Party Official
510(k) Program Manager
TUV Product Service
1775 Old Highway 8
New Brighton, MN 55112-1891

Re: k033601
Trade/Device Name: LabOne Micro-Plate Cotinine EIA
Regulation Number: 21 CFR 862.3200
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: DLJ; MKU
Dated: January 26, 2004
Received: January 28, 2004

Dear Ms. Danielson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indication for Use Statement

510(k) Number (if known) K_____

Device Name: LabOne Micro-Plate Cotinine EIA

Indication For Use:

LabOne Micro-Plate Cotinine EIA is a competitive micro-plate immunoassay for the qualitative and semi-quantitative determination of cotinine in oral fluid collected with the OraSure® Oral Fluid Specimen Collection Device. LabOne Micro-Plate Cotinine EIA is used as an aid in the detection of cotinine after use of tobacco products or other products containing nicotine. The test is for *in Vitro* use only.

The LabOne Microplate Cotinine Calibrators are a device intended for medical purposes for use with the LabOne Microplate Cotinine assay to establish points of reference that are used in determination of values in the measurement of cotinine in saliva.

The LabOne Microplate Cotinine Controls are intended for use as an assayed quality control matrix to monitor the precision and accuracy of the laboratory testing procedures for cotinine.

✓ or _____

Prescription Over-the-Counter

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) k033601